

08/537,736


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

C/21/96

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or ~~thirty days~~, ~~whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-50 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-50 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-50 are drawn to methods for production of an organic molecule. However, the claims are not limited to any specific method of production. They are generic with respect to the number and chemical composition of the reagents from enzymes to all common reactive organic molecules to amino acids to nucleotides. They are generic with respect to the types and number of reactions. They are not specific with respect to the method by which the numerous steps of the combinatorial chemistry is carried out, whether the solid support will be beads, or reaction vessels or photo active solid surfaces. Finally, the methods are not specific with the type of "selection" one will use to isolate the desired organic molecule.

Thus, these claims read on the production of any molecule, any chemotherapy drug, any enzyme, any DNA molecule, any drug molecule with any pharmacological activity whether it dulls pain, lowers blood pressure, cures cancer or restores hair loss. All of these molecules could be made by the claimed methods and thus are within the scope of these claims.

The specification merely exemplifies the synthesis of a peptide library. The selection

Serial No. 08/537,736
Art Unit 1809

method is very straight forward. One merely screens for a desired enzymatic activity.

Lacking any more guidance it would require undue experimentation to enable a reasonable number of organic molecule production methods. One would have to work out the details of how the multiple rounds of reactions are carried out, how the various reactants are brought into contact with the growing molecule, how the waste products are washed away and how the desired product is isolated from the myriad exogenous products. One would have to develop selection schemes for diverse purposes such as pain killers, blood pressure lowering, cancer cures and restoring hair loss. Thus, in view of the lack of guidance, large claim scope and unpredictability of developing "selection schemes" it would require undue experimentation to enable a reasonable number of embodiments of these claims.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

3. Claims 1-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al., Trends Biochem., 12(1):19-26, 1/1994 (Jacobs). Note that this is a review article and so the

Serial No. 08/537,736
Art Unit 1809

relevant "prior art" date is the date of the original publication of the work not the date of publication of the review article.

Jacobs teaches: isolating from a final reaction, determination of structures (p. 21, Fig 4), repetition, a core structure, the various starting group reactants: amino acids, nucleotides, enzymes, (p. 20, fig. 2, p. 21 col. 1 and p. 24, fig 7), various selection methods p. 20, col 2 and (p. 24, col. 2), synthesis of peptides and oligonucleotides (p. 20), pools of up to 10^8 - 10^9 members (p. 20, col. 1), reduction, oxidation and condensation (p. 20, col. 2), light exposing (p. 21, fig 3). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the various techniques of Jacobs for the expected benefit of "screening extremely large numbers of molecules of potential therapeutic value (Jacobs p. 19, col.1)."

4. Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1809. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Art Unit 1809 Fax number is (703) 305-7401.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 6:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
December 23, 1996


SCOTT W. HOUTTEMAN
PATENT EXAMINER
GROUP 1800